PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 30844/30003A	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/US2005/006505	International filing date *(day/month/year)* 23.02.2005	Priority date *(day/month/year)* 23.02.2004
International Patent Classification (IPC) or national classification and IPC C12N15/82, A01H5/00		
Applicant CHROMATIN, INC. et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23.09.2005	16.02.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Chavanne, F Telephone No. +49 89 2399- 8399

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US2005/006505

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-182 as originally filed

   Sequence listings part of the description, Pages

   1-34 as originally filed

   Claims, Numbers

   1-95 as originally filed

   Drawings, Sheets

   1/6-6/6 as originally filed

   ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-95
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-95
Industrial applicability (IA)	Yes:	Claims	1-95
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Supplemental Box relating to Sequence Listing

Continuation of Box I, item 2:

1. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this report has been established on the basis of:

   a. type of material:

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☒ in written format

   ☒ in computer readable form

   c. time of filing/furnishing:

   ☒ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purposes of search and/or examination

   ☐ received by this Authority as an amendment on

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

   D1: US 2003/0124561
   D2: WO 98/55637
   D3: WO 01/11020
   D4: EP-A-0 338 266

2. Not all cells of a plant transformed with e.g. a mini-chromosome contain said mini-chromosome. Thus, the scope of claims 54 and 55 also encompasses non-transformed parts of the plant of claims 1-53. Moreover, due to the segregation during meiosis the progeny of transformed plants as defined in claims 1-53 encompasses also non-transformed plants. Therefore, claims 54-65 cannot be considered novel (Article 33(2) PCT).

3. D1 describes the construction of mini-chromosomes comprising the centromere sequence from e.g. *Brassica oleracea, Glycine max, Zea mays* or Arabidopsis and the sequences of exogenous genes of interest conferring e.g. insect or herbicide resistance. D1 mentions the production of plants, including crop plants, transformed with said mini-chromosome (abstract; paragraphs 10, 12, 23-30 and 100-205; figures 9, 10, 12; examples 1-9).
   Thus, in view of D1, the subject-matter of claims 1-95 is not novel (Article 33(2) PCT).
   D1 does not specifically mention the transmission efficiency of the mini-chromosome it describes. However, this corresponds to properties of the known mini-chromosome, and as such are implicit features of said mini-chromosome. As a general rule, the elucidation of novel properties of a known product is not able to reinstate its novelty.

4. D2 describes the identification and cloning of centromeres from Arabidopsis, and their use in the construction of stably inherited mini-chromosomes. These mini-chromosomes also contain exogenous nucleic acid sequences conferring e.g. resistance to insects or herbicides. Transgenic plants comprising said mini-chromosomes are described (abstract; page 4, line 27; page 5, lines 7-23; page 6 to

page 7, line 8; page 16, line 8 to page 20, line 3; page 34 to page 58, line 14; examples 3-5). Thus, in view of D2, the subject-matter of claims 1-95 is not novel (Article 33(2) PCT).

5. D3 describes methods for making mini-chromosomes containing genes of interest. The mini-chromosomes of D3 may contain centromere and/or telomere sequences. The transformation of Tobacco with said mini-chromosomes is also mentioned in D3 (abstract; page 2, lines 13-19; page 4, lines 19-25; pages 6 and 7; page 12, lines 19-24; page 16, lines 5-10; examples 1 and 2; figures 3 and 4).
Thus, in view of D3, the subject-matter of claims 1-9, 11-65 and 82-95 is not novel (Article 33(2) PCT).

6. D4 describes the construction of mini-chromosomes using plant telomere and centromere, and exogenous sequences such as resistance genes. Plant cells have been transformed with said mini-chromosomes (abstract; page 4, line 35 to page 5, line 16; page 12, lines 4-29; example 14; figures 7-19). Thus, in view of D4, the subject-matter of claims 54-65 is not novel (Article 33(2) PCT).

7. The matter for which protection is sought in claims 2-6 is not clearly defined. The subject-matter of claims 2-6 refers to a transformed plant and attempts to define the subject-matter in terms of a result to be achieved ("has a transmission efficiency of..."). Such a definition is only allowable under the conditions elaborated in the Guidelines C-III, 4.7 PCT. In this instance, however, such a formulation is not allowable because it appears possible to define the subject-matter in more concrete terms, viz. in how the effect is to be achieved. Therefore, claim 1 does not meet the requirements of Article 6 PCT.

8. Claim 1 lacks clarity in that the expression "adchromosomal" has no well-recognised meaning. It is an internal designations, and thus, meaningless to a person skilled in the art (Article 6 PCT).

9. The subject-matter of both claims 56 and 57 is not limited to one single product, as it should be, but refers to five and three different products, respectively (Article 6 PCT).

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No.

PCT/US2005/006505